Remarks

The above amendments have been made to remove the internal attorney docket number and replace it with the U.S. Patent Application Serial Number; and to correct typographical errors. Corrections to typographical errors in the citation to the Butterfield document have been made. Applicants submit that Butterfield's phosphate buffered water (PBW) is known in the art, and one of skill in the art would be able to locate the correct citation.

No new matter has been added as a result of these amendments.

Conclusion

The Examiner is invited to contact Applicants' Representatives at the below-listed telephone number, if there are any questions regarding this Preliminary Amendment or if prosecution of this application may be assisted thereby.

Respectfully submitted for
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CERTIFICATE UNDER 37 CFR §1.8:
The undersigned hereby certifies that this paper is being deposited with the United States Postal Service as first class mail, in an envelope addressed to: Assistant Commissioner for Patents, P.O. Box 2327, Arlington, VA 22202, on this 21 day of August, 2002.

By: Ann M Mueting
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APPENDIX A - SPECIFICATION/CLAIM AMENDMENTS INCLUDING NOTATIONS TO INDICATE CHANGES MADE
Serial No.: 10/052,158
Docket No.: 57339US002

Amendments to the following are indicated by underlining what has been added and bracketing what has been deleted. Additionally, all amendments have been marked in bold typeface.

In the Specification

The paragraph beginning at page 1, line 26, has been amended as follows:

- - It is well known that none of the commercially available skin antiseptics kill all of the bacteria on the skin. For this reason, recent products have incorporated film-forming polymers that resist wash-off during surgery or exposure to fluids. Prior art attempts to improve the length of antiseptic activity through the use of film-forming polymers is described, for example, in U.S. Pat. Nos. 4,978,527 (Brink **et al.**) and 5,763,412 (Khan **et al.**). Many of these products also require an organic remover solution or lotion to get the prep off the skin. This is inconvenient for the clinician and requires significant extra time. - -

The paragraph beginning at page 16, line 29, has been amended as follows:

- - Polymers prepared from these amine group-containing monomers in combination with long chain monomers may be pressure sensitive adhesives such as those described in Applicants' Assignee's copending U.S. Patent Application Serial No. **10/052,032** [_____], filed on even date herewith, entitled PRESSURE SENSITIVE ADHESIVES HAVING QUATERNARY AMMONIUM FUNCTIONALITY, ARTICLES, AND METHODS **[(Attorney Docket Number 56435US002)]**. - -

The paragraph beginning at page 18, line 29, has been amended as follows:

- - Certain of the film-forming vinyl polymers of the present invention are themselves antimicrobial (i.e., they are inherently antimicrobial). U.S. Pat. No. 5,408,022 (Imazato **et al.**) teaches that certan quaternary amine functional polyacrylates have antimicrobial activity. In general, these include quaternary amine groups containing at least one organic moiety having at least 6 contiguous carbon atoms. Surprisingly, it has been discovered that acrylic polymers based on short chain quaternary ammonium groups (all 4 organic substituents having less than 6 contiguous carbon atoms) can also have significant antimicrobial activity if copolymerized with monomers having alkyl groups having at least 8, and preferably at least 12 contiguous carbon atoms. Preferably, the alkyl groups have at most 22 carbon atoms, and more preferably at most 18 carbon atoms. For example, polyacrylate polymers based on trimethylaminoethyl methacrylate and 2-ethylhexyl acrylate show surprising antimicrobial activity. In addition, polyacrylate polymers based on trimethylaminoethyl methacrylate chloride salt and lauryl methacrylate appear to have even higher antimicrobial activity. In particular, polymers based on trimethylaminoethyl methacrylate chloride salt, lauryl methacrylate, and methyl methacrylate are particularly effective antimicrobial agents. - -

The paragraph beginning at page 22, line 16, has been amended as follows:

- - Examples of antimicrobial agents include iodine and its complexed forms, which are commonly referred to as iodophors. Iodophors are complexes of elemental iodine or triiodide with certain carriers. These iodophors function to not only increase the iodine solubility but to reduce the level of free molecular iodine in solution and to provide a type of sustained release reservoir of iodine. Iodophors have been formed using carriers of polymers such as polyvinylpyrrolidone (PVP), copolymers of N-vinyl lactams with other unsaturated monomers

such as, but not limited to, acrylates and acrylamides, various polyether glycols (PEGs) including polyether-containing surfactants such as nonylphenolethoxylates and the like, polyvinyl alcohols, polycarboxylic acids such as polyacrylic acid, polyacrylamides, polysaccharides such as dextrose, and the like. Also reported in U.S. Pat. No. **[4,957,975]** **4,597,975** (Woodward **et al.**) are protonated amine oxide surfactant-triiodide complexes that are also suitable iodophors for use in the present invention. - -

The paragraph beginning at page 27, line 16, has been amended as follows:

- - *6. Alkyl Polyglucosides.* Alkyl polyglucosides, such as those described in U.S. Pat. No. 5,951,993 (Scholz **et al.**), starting at column 9, line 44, are compatible with the film-forming polymers of the present invention and may contribute to polymer stability. Examples include glucopon 425, which has a (C8-C16)alkyl chain length with an average chain length of 10.3 carbons and 1-4 glucose units. - -

The paragraph beginning at page 34, line 6, has been amended as follows:

- - Suitable hydroxycarboxylic acid buffers include those described in Applicants' Assignee's copending U.S. Patent Application Serial No. **10/051,719** **[_____]**, entitled ANTISEPTIC COMPOSITIONS AND METHODS **[(Attorney Docket No. 57338US002)]**. - -

The paragraph beginning at page 34, line 10, has been amended as follows:

- - The hydroxycarboxylic acid buffers of the present invention preferably include beta- and alpha-hydroxy acids (BHAs, AHAs, respectively, collectively referred to as hydroxy acids (HAs)), their salts, lactones, and/or derivatives thereof. These may include mono-, di-, and tri-functional carboxylic acids. Particularly preferred are HAs having 1 or 2 hydroxyl groups and 1

or 2 carboxylic acid groups. Suitable HAs include, but are not limited to, lactic acid, malic acid, citric acid, 2-hydroxybutanoic acid, 3-hydroxybutanoic acid, mandelic acid, gluconic acid, tartaric acid, salicylic acid, as well as derivatives thereof (e.g., compounds substituted with hydroxyls, phenyl groups, hydroxyphenyl groups, alkyl groups, halogens, as well as combinations thereof)). Preferred HAs include lactic acid, malic acid, and citric acid. These acids may be in D, L, or DL form and may be present as free acids, lactones, or salts thereof. Other suitable HAs are described in U.S. Pat. No. 5,665,776 (Yu **et al.**). The preferred HAs for use with iodine and in particular with povidone-iodine are lactic and malic acid. Various combinations of hydroxycarboxylic acids can be used if desired. - -

The paragraph beginning at page 35, line 14, has been amended as follows:

- - In addition to hydroxycarboxylic acid buffers, a variety of other ingredients may be added to the compositions of the present invention for desired effect. These include, but are not limited to, skin emollients and humectants such as those described in U.S. Pat. No. 5,951,993 (Scholz **et al.**), fragrances, colorants, tackifiers, plasticizers, etc. - -

The paragraph beginning at page 50, line 28, has been amended as follows:

- - Compositions were evaluated for their potential for eye irritation compared to commercially available antiseptics: BETADINE Surgical Scrub (7.5% povidone- iodine) and BETADINE Sterile Ophthalmic Prep Solution (5% povidone-iodine). The test involved instilling into the eyes of adult New Zealand White albino rabbits weighing 2.0-3.5 Kg of either sex. Proper husbandry of the animals prior to testing is ensured including clean housing, high fiber rabbit diets (No. 5326 Purina Mills, Inc.), proper clean watering, proper environmental control (16°C-22°C, 30%-70% relative humidity, and a 12 hour light/12 hour dark cycle). All animals were acclimated for at least 5 days and were given various cage-enrichment devices. Eyes were

examined using sodium fluorscein dye on the day before the test material administration to ensure no sign of corneal injury or eye abnormality was present. Each test material was administered to three rabbits with 0.1 mL of undiluted test material/eye for two consecutive days. The eyelids were gently held together for 1 second before releasing to prevent loss of the material. The eyes of the rabbits remained unflushed for approximately 24 hours following instillation of the test material. The right eye of each animal was treated while the left eye remained untreated as a control. The eyes were examined for ocular irritation at 1, 4, 24, 48, and 72 hours after their respective treatment. Additional observations were made at 96 and 120 hours if irritation was present at 72 hours. Sodium Fluoroscein was used to aide in revealing possible corneal injury for each animal beginning with the 24-hour examination and each continuing examination until a negative response was attained. Irritation was scored using the Ocular Draize Technique (J. H. Draize: "Dermal Toxicity," **["Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics"]** ***Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics***, Association of Food and Drug Officials of the U.S., 1959, pages **46-59 [59-51]**) with some modification. The maximum total score for these examples was the sum of scores obtained only from the conjunctivae. Total maximum score possible is 60 (20 per eye times three eyes). Notes were made with respect to the Cornea opacity, but this was not included in the scoring. - -

The paragraph beginning at page 92, line 14, has been amended as follows:

- - The composition of Example 14 was absorbed to saturation in gauze and applied to the inner forearm of a volunteer by simply painting the formulation on the arm 3 times in a continuous circular motion. The prep was allowed to stay in place for at least 2 minutes after which time a glass-sampling cylinder with an area of 5.04 cm^2 was pressed to the skin over the prep. Into this sampling cylinder was dispensed 2.5 mL sterile sampling solution. The sampling solution was mixed thoroughly in the glass cylinder on the arm using a TEFLON policeman for 1